



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

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May 12, 2004

Christopher F. Robertson, Esq.
Seyfarth Shaw LLP
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Two Seaport Lane Suite 300
Boston, MA 02210-2028

Dear Mr. Robertson,

The Food and Drug Administration has received your letter dated May 10, 2004 sent on behalf of ITV Direct, Inc. and Direct Marketing Concepts, Inc. located in Beverly, MA in response to NWE-DO Warning Letter (NWE-25-04W) issued on April 19, 2004.

The proposed corrective action described in the letter appears to be adequate.

This letter is not intended to be an unconditional endorsement of your client's operating practices in their entirety. It is an ongoing obligation of your client to ensure that the firm operates in compliance with applicable regulations and laws enforced by FDA. Your client's promotional practices, to the extent that they fall under FDA jurisdiction, are subject to ongoing scrutiny and review.

If you have any additional questions, you should contact me at 781-596-7758.

Sincerely,

M. Patricia Murphy
M. Patricia Murphy
Compliance Officer
New England District